K002866

BIO-RAD **Bio-Rad Laboratories**

Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Telephone: (949) 598-1200

SEP 25 2000

510(k) Summary

Submitter
Bio-Rad Laboratories
9500 Jeronimo Road
Irvine, CA
(949)598-1285
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Contact Person
Elizabeth Platt

Date of Summary Preparation
September 11, 2000

Device (Trade & Common Name)
Liquichek Blood Gas Plus E Control Level 4

Classification Name
Class I, JJS
CFR 862.1660: Controls for Blood Gases, (Assayed and Unassayed)

Devices to Which Substantial Equivalence is Claimed
Liquichek Blood Gas Control
Bio-Rad Laboratories
Irvine, California
K002120

Statement of Intended Use
Liquichek Blood Gas Plus E Control Level 4 is intended for use as an assayed quality control to monitor the precision of an individual laboratory's measurement of pH, pCO2, elevated pO2, and electrolytes by blood gas and ion selective electrode (ISE) instrumentation.

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Description of the Device

Liquichek Blood Gas Plus E Control Level 4 is a buffered bicarbonate and electrolyte solution in equilibrium with predetermined levels of oxygen, carbon dioxide and nitrogen.

Statement of How Technological Characteristics Compare to Substantial Equivalent Device

A table is provided below comparing the similarities between the Bio-Rad Liquichek Blood Gas Plus E Control Level 4 and the device to which substantial equivalence is claimed.

	Bio-Rad Liquichek Blood Gas Plus E Control Level 4 (New Device)	Bio-Rad Liquichek Blood Gas Control (Substantially Equivalent Device)
Intended Use	An assayed quality control material for use in monitoring the precision of an individual laboratory's measurement of pH, pCO2, elevated pO2 and electrolytes by blood gas and ion selective electrode (ISE) instrumentation.	An assayed quality control for use in monitoring the precision of an individual laboratory's measurement of pH, pCO2, and pO2 by blood gas instrumentation.
Form	Liquid	Liquid
Matrix	Buffered bicarbonate and electrolyte solution	Buffered bicarbonate solution
Levels	One	One
Storage	Room temperature (15-30°C)	Room temperature (15-30°C)
Analytes	Same as substantial equivalence plus the following: ionized calcium, chloride, potassium and sodium.	pH, pCO2, pO2

Open Vial Claim	When the control is used for pH and blood gas measurements, the material should be sampled immediately after opening. When used only for electrolyte measurements, the material should be sampled within 10 minutes of opening to avoid evaporation. Once the control is sampled, discard remaining material.	Once opened, all analytes should be assayed immediately; discard the remaining material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 25 2000

Ms. Elizabeth Platt
Regulatory Affairs Manager
Bio-Rad Laboratories
Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017

Re: K002866
Trade Name: Liquichek Blood Gas Plus E Control Level 4
Regulatory Class: I reserved
Product Code: JJS
Dated: September 11, 2000
Received: September 13, 2000

Dear Ms. Platt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K002866

Device Name: **Liquichek Blood Gas Plus E Control Level 4**

Indications for Use:

Liquichek Blood Gas Plus E Control Level 4 is intended for use as an assayed quality control to monitor the precision of an individual laboratory's measurement of pH, pCO2, elevated pO2, and electrolytes by blood gas and ion selective electrode (ISE) instrumentation.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory
510(k) Number K002866

(PLEASE DO NOT WRITE BELOW THE LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Concurrence of CDRH, Office of Device Evaluation)

Prescription Use ✓ OR Over-The Counter Use _____